VACCINE INFORMATION STATEMENT

Influenza Vaccine Inactivated

What You Need to Know

1 Why get vaccinated?

Influenza ("flu") is a contagious disease.

It is caused by the influenza virus, which can be spread by coughing, sneezing, or nasal secretions.

Anyone can get influenza, but rates of infection are highest among children. For most people, symptoms last only a few days. They include:

- · fever/chills
- · sore throat
- muscle aches fatigue

- cough
- headache
- · runny or stuffy nose

Other illnesses can have the same symptoms and are often mistaken for influenza.

Young children, people 65 and older, pregnant women, and people with certain health conditions — such as heart, lung or kidney disease, or a weakened immune system — can get much sicker. Flu can cause high fever and pneumonia, and make existing medical conditions worse. It can cause diarrhea and seizures in children. Each year thousands of people die from influenza and even more require hospitalization.

By getting flu vaccine you can protect yourself from influenza and may also avoid spreading influenza to others.

2 Inactivated influenza vaccine

There are two types of influenza vaccine:

- 1. **Inactivated** (killed) vaccine, the "flu shot," is given by injection with a needle.
- 2. **Live, attenuated** (weakened) influenza vaccine is sprayed into the nostrils. *This vaccine is described in a separate Vaccine Information Statement.*

A "high-dose" inactivated influenza vaccine is available for people 65 years of age and older. Ask your doctor for more information.

Influenza viruses are always changing, so annual vaccination is recommended. Each year scientists try to match the viruses in the vaccine to those most likely to cause flu that year. Flu vaccine will not prevent disease from other viruses, including flu viruses not contained in the vaccine.

It takes up to 2 weeks for protection to develop after the shot. Protection lasts about a year.

2012 - 2013

Many Vaccine Information Statements are available in Spanish and other languages.

See www.immunize.org/vis.

Hojas de Informacián Sobre Vacunas están disponibles en Español y en muchos otros idiomas. Visite http://www.immunize.org/vis

Some inactivated influenza vaccine contains a preservative called thimerosal. Thimerosal-free influenza vaccine is available. Ask your doctor for more information.

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Who should get inactivated influenza vaccine and when?

WHO

All people 6 months of age and older should get flu vaccine.

Vaccination is especially important for people at higher risk of severe influenza and their close contacts, including healthcare personnel and close contacts of children younger than 6 months.

WHEN

Get the vaccine as soon as it is available. This should provide protection if the flu season comes early. You can get the vaccine as long as illness is occurring in your community.

Influenza can occur at any time, but most influenza occurs from October through May. In recent seasons, most infections have occurred in January and February. Getting vaccinated in December, or even later, will still be beneficial in most years.

Adults and older children need one dose of influenza vaccine each year. But some children younger than 9 years of age need two doses to be protected. Ask your doctor,

Influenza vaccine may be given at the same time as other vaccines, including pneumococcal vaccine.



Some people should not get inactivated influenza vaccine or should wait.

 Tell your doctor if you have any severe (lifethreatening) allergies, including a severe allergy to eggs. A severe allergy to any vaccine component may be a reason not to get the vaccine. Allergic reactions to influenza vaccine are rare.



- Tell your doctor if you ever had a severe reaction after a dose of influenza vaccine.
- Tell your doctor if you ever had Guillain-Barré
 Syndrome (a severe paralytic illness, also called GBS).
 Your doctor will help you decide whether the vaccine
 is recommended for you.
- People who are moderately or severely ill should usually
 wait until they recover before getting flu vaccine. If you are
 ill, talk to your doctor about whether to reschedule the
 vaccination. People with a mild illness can usually get the
 vaccine.

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What are the risks from inactivated influenza vaccine?

A vaccine, like any medicine, could possibly cause serious problems, such as severe allergic reactions. The risk of a vaccine causing serious harm, or death, is extremely small.

Serious problems from inactivated influenza vaccine are very rare. The viruses in inactivated influenza vaccine have been killed, so you cannot get influenza from the vaccine.

Mild problems:

- · soreness, redness, or swelling where the shot was given
- hoarseness; sore, red or itchy eyes; cough
- fever aches headache itching fatigue If these problems occur, they usually begin soon after the shot and last 1-2 days.

Moderate problems:

Young children who get inactivated flu vaccine and pneumococcal vaccine (PCV13) at the same time appear to be at increased risk for seizures caused by fever. Ask your doctor for more information.

Tell your doctor if a child who is getting flu vaccine has ever had a seizure.

Severe problems:

- Life-threatening allergic reactions from vaccines are very rare. If they do occur, it is usually within a few minutes to a few hours after the shot.
- In 1976, a type of inactivated influenza (swine flu) vaccine was associated with Guillain-Barré Syndrome (GBS). Since then, flu vaccines have not been clearly linked to GBS. However, if there is a risk of GBS from current flu vaccines, it would be no more than 1 or 2 cases per million people vaccinated. This is much lower than the risk of severe influenza, which can be prevented by vaccination.

The safety of vaccines is always being monitored. For more information, visit:

www.cdc.gov/vaccinesafety/Vaccine_Monitoring/Index.html and

www.cdc.gov/vaccinesafety/Activities/Activities_Index.html

One brand of inactivated flu vaccine, called Affuria, **should not be given** to children 8 years of age or younger, except in special circumstances. A related vaccine was associated with fevers and fever-related seizures in young children in Australia. Your doctor can give you more information.

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What if there is a severe reaction?

What should I look for?

 Any unusual condition, such as a high fever or unusual behavior. Signs of a serious allergic reaction can include difficulty breathing, hoarseness or wheezing, hives, paleness, weakness, a fast heart beat or dizziness.

What should I do?

- · Call a doctor, or get the person to a doctor right away.
- Tell your doctor what happened, the date and time it happened, and when the vaccination was given.
- Ask your doctor, nurse, or health department to report the reaction by filing a Vaccine Adverse Event Reporting System (VAERS) form. Or you can file this report through the VAERS web site at www.vaers.hhs.gov, or by calling 1-800-822-7967.

VAERS does not provide medical advice.



The National Vaccine Injury Compensation Program

The National Vaccine Injury Compensation Program (VICP) was created in 1986.

People who believe they may have been injured by a vaccine can learn about the program and about filing a claim by calling 1-800-338-2382 or visiting the VICP website at www.hrsa.gov/vaccinecompensation.

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How can I learn more?

- Ask your doctor. They can give you the vaccine package insert or suggest other sources of information.
- · Call your local or state health department.
- Contact the Centers for Disease Control and Prevention (CDC):
 - Call 1-800-232-4636 (1-800-CDC-INFO) or
 - Visit CDC's website at www.cdc.gov/flu

Vaccine Information Statement (Interim)

Influenza Vaccine

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